DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

Covidien
Ms. Sharon McDermott
Senior Product Regulatory Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K143161
Trade/Device Name: Force FX Generators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 4, 2014
Received: December 5, 2014

Dear Ms. McDermott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143161

Device Name
Force FX Generators

Indications for Use *(Describe)*

The Force FX™ Electrosurgical Generator is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting (resecting, dividing, or separating) and coagulating (hemostasis).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

COVIDIEN

510(k) Summary

Date summary prepared: December 18, 2014

510(k) Submitter/Holder
Covidien (formerly Valleylab, Inc.)
5920 Longbow Drive
Boulder, CO 80301

Contact
Sharon McDermott
Sr. Regulatory Affairs Product Specialist
Telephone: 303-581-6789
Fax: 303-530-6313
Email: sharon.mcdermott@covidien.com

Name of Device

Trade Name:	Force FX™ electrosurgical generators
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, class II, GEI)

Predicate Device

Trade Name:	Force FX
Common Name:	Electrosurgical Generator
Catalog Number:	Force FX
510(k) Number:	K944602 (cleared 6/5/1995)
Manufacturer:	Covidien

Device Description

The Force FX™ Electrosurgical Generators are microcontroller-based isolated output generators that provide power for cutting, desiccating, and fulgurating tissue during bipolar and monopolar surgery. Features included are:

- Instant Response™ Technology - Automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density.
- Three bipolar modes: precise, standard, and macro - Low voltage, continuous current provides faster desiccation without sparking.
- Three monopolar Cut modes: low, pure, blend - Allows a wide range of power settings necessary to perform diverse surgical procedures.
- Three monopolar Coag modes: desiccate, fulgurate, and spray - Helps control the size of the area and the depth of penetration during tissue coagulation.
- Support for Simultaneous Activation
- Covidien Energy-based Devices REM™ Contact Quality Monitoring System - Monitors the quality of electrical contact between the return electrode and the patient to eliminate risk of pad site burns.
- Handswitch or footswitch activation
- Recall of most recently used mode and power settings

- Adjustable activation tone volume
- An RF activation port, RS-232 serial port, and expansion port

The precise and standard bipolar modes of the Force FX™-8CA(S) models are equipped with an Autobipolar function. The autobipolar feature senses tissue impedance between the two bipolar electrodes and then uses the impedance information to automatically start or stop bipolar RF activation. Optionally, the user may choose between footswitch start and auto start, or program a delay between auto start and RF activation.

Indications for Use

The Force FX™ Electrosurgical Generator is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting (resecting, dividing, or separating) and coagulating (hemostasis).

Technological Characteristics

The Force FX generators have the same technological and performance characteristics as the predicate, K944602. This Special 510(k) proposes changes to five printed circuit board assemblies (PCBAs), firmware/software, and a minor modification to the simultaneous (coag) activation tone. The function of the devices has not changed.

Performance Characteristics

The modifications made to the Force FX generator were found to not affect safety or performance through design verification testing, which confirmed the continued conformance to applicable technical design specifications and performance requirements, including requirements associated with industry safety and performance standards, as follows:

- Basic safety and essential performance in accordance with IEC 60601-1:2005 and IEC 60601-2-2:2009
- Electromagnetic compatibility in accordance with IEC 60601-1-2:2007
- Design verification testing including application of multiple AC mains voltages and temperatures to ensure the proposed modifications perform within design parameters under varying environmental conditions.
- Software regression/validation

Clinical Studies

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusions

The intended use of the Force FX generator was not altered. In addition, the results of testing demonstrate that the modifications to the Force FX generator do not affect the safety or performance of the generator which is substantially equivalent to the predicate Force FX.